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EXAMINER	
WHISENANT, ETHAN C	

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1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,963	LEXOW, PREBEN	
	Examiner	Art Unit	
	Ethan Whisenant	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 29-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,29-33 and 35-40* is/are rejected.

7)☒ Claim(s) *34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/886,223.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

NON-FINAL ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 04 OCT 08 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendment filed 04 SEP 08 has now been entered. **Claim(s) 26,29-40** is/are now pending.

Deleted: ¶

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> **(e)** the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
> or
> **(e)** the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

CLAIM REJECTIONS UNDER 35 USC § 102

4. Claim(s) 26, 29-30 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Clausen et al. [US 5,068,191 (1991)].

Claim 26 is drawn to method of sequencing all or part of a target nucleic acid molecule comprising three steps : To begin, the sequence of a portion of said target nucleic acid molecule is determined by identifying magnifying tags associated with said portion of the target nucleic acid molecule, wherein said magnifying tags are not part of the native target nucleic acid molecule and represent a detectable signal or sequence that corresponds to one or more bases of said portion. Next the position of said portion within said target nucleic acid molecule is determined, wherein said position is determined by reference to a positional marker or wherein said position is determined by reference to a restriction map of said target nucleic acid molecule. Finally, the information obtained in steps 1 and 2 is combined to obtain the sequence of all or part of said target nucleic acid molecule.

Clausen et al. teach a method of sequencing all or part of a target nucleic acid molecule which comprises all of the limitations recited in Claim 26. See at least for example, Figure 2 and note the restriction map on the right. Note that Clausen et al. teach sequencing their target nucleic acid molecules as described by Sanger et al. [PNAS 74(12) : 5463-5467(1977)]. As regards, the magnifying tags they are the labelled dATP*s incorporated into sequencing ladders as described by Sanger et al. which is the method used by Clausen et al to sequence the target nucleic acid depicted in Figure 2. Finally, note that labeled dATP* is not part of the native target nucleic acid.

Claim 29 is drawn to an embodiment of the method of Claim 26 wherein the portion sequenced has 4 or more nucleotide bases and/ or the position of said

portion within said target nucleic acid molecule is determined with an accuracy of less than 1 kb.

Clausen et al. teach these limitations. See, at least, for example Figure 1b.

Claim 30 is drawn to an embodiment of the method of Claim 26 wherein the portion is sequenced by identifying magnifying tags associated with the target nucleic acid wherein said wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region, wherein said adapter binding region binds an adapter molecule which comprises:(i) one or more of said magnifying tags, or (ii) a means for attaching one or more of said magnifying tags.

. Clausen et al. teach these limitations. See, at least, for example Figure 1b. As each base of the sequencing ladder generated by the method of Sanger et al. is determined a magnifying tag is identified. As regards the limitation which reads "wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region". The labeled ATPs incorporated into the sequencing ladders of Sanger et al. correspond to one or more bases of an adapter binding region (i.e. the primer binding sequence) or to one or more bases in proximity to an adapter binding region in that both/ all comprise deoxyribonucleic acid. As regards the limitation which reads "wherein said adapter binding region binds an adapter molecule which comprises:(i) one or more of said magnifying tags, or (ii) a means for attaching one or more of said magnifying tags". The primer binding site(s) is equivalent to the adapter binding region and the primer is equivalent to the adapter molecule. The primer of Sanger et al. (i.e. the adapter molecule) comprises a means for attaching one or more of said magnifying tags (i.e. the polymerase extendable 3' hydroxyl group on each primer).

5. Claim(s) 26, 29 and 31-33 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Drmanac et al. [Science 260 : 1649-1652 (1993)].

Claim 26 is drawn to method of sequencing all or part of a target nucleic acid molecule comprising three steps : To begin, the sequence of a portion of said target nucleic acid molecule is determined by identifying magnifying tags associated with said portion of the target nucleic acid molecule, wherein said magnifying tags are not part of the native target nucleic acid molecule and represent a detectable signal or sequence that corresponds to one or more bases of said portion. Next the position of said portion within said target nucleic acid molecule is determined, wherein said position is determined by reference to a positional marker or wherein said position is determined by reference to a restriction map of said target nucleic acid molecule. Finally, the information obtained in steps 1 and 2 is combined to obtain the sequence of all or part of said target nucleic acid molecule.

Drmanac et al. teach a method of sequencing which comprises all of the limitations of Claims 26. See, at least, for example, the legend of Figure 2. Each of the positively hybridizing probes of Drmanac et al. are the magnifying tags which "magnifying tags are associated with said portion of the target nucleic acid molecule, wherein said magnifying tags are not part of the native target nucleic acid molecule and represent a detectable signal or sequence that corresponds to one or more bases of said portion". Also each positively hybridizing probes serves as a positional marker used to assemble the sequence pf the entire target nucleic acid.

Claim 29 is drawn to an embodiment of the method of Claim 26 wherein the portion sequenced has 4 or more nucleotide bases and/ or the position of said portion within said target nucleic acid molecule is determined with an accuracy of less than 1 kb.

Drmanac et al. teach these limitations. See, at least, for example Figure 2.

Claim 31 is drawn to an embodiment of the method of Claim 26 wherein the sequence of the target nucleic acid molecule is determined by assessing the complementary of a portion of said target nucleic acid molecule by a process

comprising the steps of: (i) treating said target nucleic acid molecule so that at least a region of said target nucleic acid molecule is converted into a form suitable for binding a complementary probe, wherein said complementary probe is bound to a solid support or said complementary probe carries a means for attaching to a solid support; (ii) binding said complementary probe to at least a portion of said region suitable for binding a complementary probe; (iii) optionally repeating steps (i) and (ii), with the *proviso* that said complementary probe binds to an adjacent or overlapping region of said target nucleic acid molecule relative to the region to which the complementary probe of the previous cycle bound; and (iv) determining the sequence of said target nucleic acid molecule by identifying the complementary probe(s) to which said target nucleic acid molecule bound.

Drmanac et al. teach all of these limitations. See, at least, for example Figure 2.

Claim 32 is drawn to an embodiment of the method of Claim 31 wherein in step (i) said form is a single-stranded nucleic acid molecule. **Claim 33** is drawn to an embodiment of the method of Claim 31 wherein in step (ii) said portion is 4 to 12 nucleotide bases in length.

Drmanac et al. teach all of these limitations. See, at least, for example Figure 2.

6. Claim(s) 36-39 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Brenner et al. [US 5,695,934 (1997)].

Claim 36 is drawn to method of producing a map of a target nucleic acid molecule comprising the steps of: (A) obtaining sequence information on portions of a target nucleic acid molecule by cleaving said target nucleic acid molecule with one or more nucleases; and (B) binding an adapter molecule to a region of said target nucleic acid molecule, wherein said adapter molecule comprises one or more magnifying tags as claimed in claim 26, wherein each tag comprises: (i) a first signaling moiety which corresponds to one or more bases of said region to which said adapter molecule binds,

and (ii) a second signaling moiety which corresponds to a nuclease used for cleavage, wherein said portions comprise all or part of the cleavage sites of said nucleases and/or all or part of the restriction sites of said nucleases; and (C) determining the position of said portions within said target nucleic acid molecule so to produce a map of the target nucleic acid molecule.

Brenner et al. teach a method of producing a map of a target nucleic acid molecule which comprises all of the limitations recited in Claim 36, see at least for example Figure 2. The magnifying tag in Brenner is the Type IIs restriction enzyme recognition sequence in the adapter, see elements "9" and "17" of Figure 2. As regards the limitation in step (C) which reads determining the position of said portions within said target nucleic acid molecule so to produce a map of the target nucleic acid molecule. This limitation is inherent to the sequencing method of Brenner in that as each base (i.e. portion) of a target nucleic acid sequence is determined its position within the target nucleic acid is necessarily determined.

Claim 37 is drawn to an embodiment of the method of Claim 36 wherein said nuclease has a cleavage site which is separate from its recognition site.

Brenner et al. teach this limitation, see at least for example Figure 2.

Claim 38 is drawn to an embodiment of the method of Claim 36 wherein said cleaving produces complementary single-stranded regions.

Brenner et al. teach this limitation, see at least for example Figure 2.

Claim 39 is drawn to a method of sequencing all or part of a target nucleic acid molecule comprising the steps of: (A) determining the sequence of a portion of said target nucleic acid molecule; (B) determining the position of said portion within said target nucleic acid molecule; and (C) combining the information obtained in steps (A)

and (B) to obtain the sequence of all or part of said target nucleic acid molecule, wherein step (B) is carried out by identifying a label which is incorporated into or onto said portion of said target nucleic acid molecule and which indicates the position of said portion within said target nucleic acid molecule.

Brenner et al. teach a method of producing of sequencing all or part of a target nucleic acid molecule which comprises all of the limitations recited in Claim 39, see at least for example Figure 2. As regards the limitation in step (B) which reads "determining the position of said portion within said target nucleic acid molecule". This limitation is inherent to the sequencing method of Brenner in that as each base (i.e. portion) of a target nucleic acid sequence is determined its position within the target nucleic acid is necessarily determined.

35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

8. **Claim(s) 26, 29-30, 35** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner et al. [US 5,695,934 (1997) - interpretation No. 1] in view of Clausen et al. [US 5,068,191 (1991)].

Claim 26 is drawn to method of sequencing all or part of a target nucleic acid molecule comprising three steps : To begin, the sequence of a portion of said target nucleic acid molecule is determined by identifying magnifying tags associated with said portion of the target nucleic acid molecule, wherein said magnifying tags are not part of the native target nucleic acid molecule and represent a detectable signal or sequence that corresponds to one or more bases of said portion. Next the position of said portion within said target nucleic acid molecule is determined, wherein said position is determined by reference to a positional marker or wherein said position is determined by reference to a restriction map of said target nucleic acid molecule. Finally, the information obtained in steps 1 and 2 is combined to obtain the sequence of all or part of said target nucleic acid molecule.

Brenner et al. teach a method of sequencing all or part of a target nucleic acid molecule which comprises all of the limitations recited in Claim 26 except this author does not teach determining the position of said portion within said target nucleic acid molecule by reference to a positional marker or wherein said position is determined by reference to a restriction map of said target nucleic acid molecule. However, as evidenced by at least Clausen et al. it was routine in the art to determine the position of a sequenced portion of a target nucleic acid by reference to a positional marker (e.g. a restriction site) or by reference to a restriction map. See at least for example, Figure 2 and note the restriction map on the right. As regards, the magnifying tags **(Interpretation 1)** they are the labelled dNTP*s incorporated at the 3' end of the cleaved target nucleic molecules, see the element labelled "11" in Figure 1b. Note that labeled dNTP*s are not part of the native target nucleic acid. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Brenner wherein the position of a sequenced portion of a target nucleic acid is determined by reference to a positional marker (e.g. a restriction site) or by reference to a restriction map. The use of such landmarks in compiling the sequence data of large nucleic acid molecules from multiple sequencing experiments was well known. The ordinary artisan would have been

motivated to make the modification recited above in order to help in aligning the sequence data from multiple experiments.

Claim 29 is drawn to an embodiment of the method of Claim 26 wherein the portion sequenced has 4 or more nucleotide bases and/ or the position of said portion within said target nucleic acid molecule is determined with an accuracy of less than 1 kb.

Brenner teaches this limitation, see, at least, for example, Column 2 , beginning at about line 30. In addition, Clausen et al. teach these limitations. See, at least, for example Figure 1b.

Claim 30 is drawn to an embodiment of the method of Claim 26 wherein the portion is sequenced by identifying magnifying tags associated with the target nucleic acid wherein said wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region, wherein said adapter binding region binds an adapter molecule which comprises:(i) one or more of said magnifying tags, or (ii) a means for attaching one or more of said magnifying tags.

Brenner teaches this embodiment. As regards the limitation which reads "wherein the portion is sequenced by identifying magnifying tags associated with the target nucleic acid". As each labeled dNTP (i.e. magnifying tag) is incorporated, Brenner teaches determining which base has been incorporated. As regards the limitation which reads " wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region. Note at least Figure 1b which teaches that each magnifying tag (i.e. each labeled dNTP incorporated) corresponds to one or more bases in proximity to an adapter binding region. As regards the limitation which reads "wherein said adapter binding region binds an adapter molecule which comprises:(i) one or more of said magnifying tags, or

(ii) a means for attaching one or more of said magnifying tags" note that each of the adapter molecules comprises a means (i.e. the 5' phosphate group on the adapter) for attaching one or more of said magnifying tags (i.e. each labeled dNTP incorporated-ligated during the ligation step of Brenner.

Claim 35 is drawn to an embodiment of the method of Claim 26 wherein said method is performed on a sample comprising a heterogeneous mixture of target nucleic acid molecules.

Brenner teaches this limitation, see at least for example the last line of the abstract.

9. Claim(s) 26, 29-30 and 40 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner et al. [US 5,695,934 (1997) - **interpretation No. 2**] in view of Clausen et al. [US 5,068,191 (1991)].

Claim 26 is drawn to method of sequencing all or part of a target nucleic acid molecule comprising three steps : To begin, the sequence of a portion of said target nucleic acid molecule is determined by identifying magnifying tags associated with said portion of the target nucleic acid molecule, wherein said magnifying tags are not part of the native target nucleic acid molecule and represent a detectable signal or sequence that corresponds to one or more bases of said portion. Next the position of said portion within said target nucleic acid molecule is determined, wherein said position is determined by reference to a positional marker or wherein said position is determined by reference to a restriction map of said target nucleic acid molecule. Finally, the information obtained in steps 1 and 2 is combined to obtain the sequence of all or part of said target nucleic acid molecule.

Brenner et al. teach a method of sequencing all or part of a target nucleic acid molecule which comprises all of the limitations recited in Claim 26 except this author does not teach determining the position of said portion within said target nucleic acid

molecule by reference to a positional marker or wherein said position is determined by reference to a restriction map of said target nucleic acid molecule. However, as evidenced by at least Clausen et al. it was routine in the art at the time of the invention to determine the position a sequenced portion of a target nucleic acid by reference to a positional marker (e.g. a restriction site) or by reference to a restriction map. See at least for example, Figure 2 and note the restriction map on the right. As regards, the magnifying tags **(Interpretation 2)** they are the Type IIs restriction enzyme recognition site(s) present in the adapters. See elements labelled '9" and "17" in Figure 1b. Note that the Type IIs restriction recognition site present in the adapters is not part of the native target nucleic acid. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Brenner wherein the position of a sequenced portion of a target nucleic acid is determined by reference to a positional marker (e.g. a restriction site) or by reference to a restriction map. The use of such landmarks in compiling the sequence data of large nucleic acid molecules from multiple sequencing experiments was well known. The ordinary artisan would have been motivated to make the modification recited above in order to help in aligning the sequence data from multiple experiments.

Finally, as regards the limitation which reads "identifying magnifying tags" this limitation is carried out by the Type IIs restriction enzyme use in the method of Brenner.

Claim 29 is drawn to an embodiment of the method of Claim 26 wherein the portion sequenced has 4 or more nucleotide bases and/ or the position of said portion within said target nucleic acid molecule is determined with an accuracy of less than 1 kb.

Brenner teaches this limitation, see, at least, for example, Column 2 , beginning at about line 30. In addition, Clausen et al. teach these limitations. See, at least, for example Figure 1b.

Claim 30 is drawn to an embodiment of the method of Claim 26 wherein the portion is sequenced by identifying magnifying tags associated with the target nucleic acid wherein said wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region, wherein said adapter binding region binds an adapter molecule which comprises:(i) one or more of said magnifying tags, or (ii) a means for attaching one or more of said magnifying tags.

Brenner teaches this embodiment. As regards the limitation which reads "wherein the portion is sequenced by identifying magnifying tags associated with the target nucleic acid". Said identifying in Brenner occurs with each round of incorporation of labeled dNTP wherein the Type IIs restriction enzyme recognizes (i.e. identifies) the restriction enzyme recognition site within the adapter molecule. As regards the limitation which reads " wherein said magnifying tags correspond to one or more bases of an adapter binding region or to one or more bases in proximity to an adapter binding region ". Note that each magnifying tag (i.e. each Type IIs restriction enzyme recognition site) corresponds to one or more bases of an adapter binding region. As regards the limitation which reads "wherein said adapter binding region binds an adapter molecule which comprises:(i) one or more of said magnifying tags, or (ii) a means for attaching one or more of said magnifying tags" note that each of the adapter molecules of Brenner comprises one or more of said magnifying tags (i.e. the Type IIs restriction enzyme recognition site).

Claim 40 is drawn to an embodiment of the method of Claim 26 wherein said magnifying tags comprise a nucleic acid sequence of at least two nucleotide bases

Brenner teaches this limitation, all Type IIs restriction enzymes have enzyme recognition sites (i.e. the magnifying tags) comprising nucleic acid sequence of at least two nucleotide bases. See for example Szybalski et al. [Gene 100 : 13-26 (1991)].

CLAIM OBJECTIONS

10. **Claim(s) 34** is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

9. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

CONCLUSION

11. **Claim(s) 26 and 29-40** is/are rejected and/or objected to for the reason(s) set forth above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634